Practical Decision Making Tools for Identifying Safer Alternatives

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Summary of Session Three: Facilitated Discussion

The Office of Environmental Health Hazard Assessment (OEHHA) prepared this summary based on notes developed by Amy D. Kyle <adkyle@berkeley.edu>, Session Three's facilitator. The summary captures the suggestions of the panel members and audience in response to the discussion questions posed. The questions were designed to elicit comments about what OEHHA could do to better carry out certain statutorily mandated activities that involve listing "bad actor" chemicals and identifying safer alternatives. However, some of the responses ranged to the larger issue of what Cal/EPA and other state agencies should do to advance the California Green Chemistry Initiative. The notes capture specific suggestions for OEHHA as well as broader advice for California.

I. What would you recommend that OEHHA do now to improve its ability to identify "bad actor" chemicals, using existing resources and methods?

Evaluate what has worked elsewhere (Canada, EU, other states) and look at the chemicals of particular interest to California.

Take advantage of the work done by the Canadians in their review of the 23,000 substances on their Domestic Substances List. Use the toxicity summaries they have generated and the relevant data they have collected.

Embrace the idea of screening of chemicals to get meaningful information and results in a reasonable amount of time. Methods for screening may be different than for full testing.

Develop greater expertise in the uses of the QSAR (quantitative structure-activity relationship) and related models and see what can be gained from using such models.

Develop a map of chemical use in California that shows where chemicals come from, how they are used, and where they go.

Get creative with the use of the information available from sources such as the US EPA Inventory Update Rule, data about imports, and so on.

Address control of the use of chemicals that pose hazards, not just focus on developing data.

Develop criteria for defining what a "bad actor" is and, conversely, what isn't (e.g., specific toxicity and exposure potential criteria).

Create and publish lists of higher and lower hazard chemicals.

Review and consider the use of more sophisticated and informative Bayesian-like methods for decision-making.

Develop approaches that better address the significance of levels of biological activity as ways to predict and understand toxicity and potency, along the lines of the recommendations from the National Academy of Sciences.

Talk to chemistry departments at universities so that they understand the importance of the hazard traits of toxicity, persistence, and bioaccumulation. Encourage the development of new curriculum and requirements for chemistry undergraduate and graduate students.

Engage stakeholders early in the process of developing proposed approaches.

Include variability and differential human susceptibility in the models and approaches. We know that there are distributions of many of the factors that predict human response to chemicals. We have not fully integrated these issues into the ways that we think about chemicals, and we need to.

Lower the barrier to obtaining access to data and create incentives for the production of data, rather than maintaining the current framework which actually provides incentives to avoid producing data.

Create lists of chemicals of concern at different levels of evidence or certainty. There may be chemicals that are of concern as possible toxic air contaminants or carcinogens but that do not make it onto the lists of the Toxic Air Contaminants or the Proposition 65 chemicals, for example. There could be "feeder" lists that would help us have an early view on what the potential chemicals of concern are.

Focus more on what people are exposed to in the real world.

Focus more on products and the chemicals in products, which get little attention.

Develop and apply expertise in decision analysis and the value of information.

Develop hazard-based criteria to motivate actions.

II. What would you recommend that OEHHA do to improve its ability over the longer term to identify "bad actor" chemicals, with the thought that additional resources or authorities could be obtained if justified?

Think deeply about the "services" that are provided by chemicals and whether there are other safer ways to provide some of these "services." There are analogies in the field of energy, where the breakthroughs came after we started to think not about new sources of energy, but how to conserve rather than use energy.

Create a system where the incentives favor the production of information, rather than the current system where the incentives favor not producing information about chemical hazard and other traits.

Overcome gaps in education related to new methods. Some of these may include computational toxicology and bioinformatics, as well as other things that we have discussed. Building such capacity (e.g., more training, resources, scientists) may lead to better models and approaches.

Educate the public and consumers and other users of products about how to select and use "safer" products. We need to address their information needs in ways that are understandable to make it possible for them to do so.

Understand the information needed by businesses using chemicals to make informed choices and evaluate how to address these information needs throughout the supply chain (i.e., information transfer up and down the supply chain between manufacturers to chemical users).

Encourage greater collaboration and partnership across disciplines and institutions to increase overall knowledge. For example, consider the model of how pharmaceutical companies make decisions on which chemicals are too hazardous to pursue.

Reduce the differences in the ways that we treat pharmaceuticals and environmental chemicals. The workshop identified several areas where information and methods developed in the

pharmaceutical industry could be useful for environmental chemicals, and these should be addressed.

Consider how to integrate multiple sources of information that apply at different stages in useful ways. We want to obtain and consider information about chemicals at the outset but also to monitor and assess environmental conditions, including biomonitoring, and to conduct public health surveillance so that we understand patterns of disease. This can allow for feedback to the original decisions and produce a system that is stronger overall.

Develop better screening methods, including in vitro assays for example, for studying a wider variety of hazard traits or endpoints such as reproductive and developmental effects.

Consider the impacts of the lack of specificity and/or sensitivity of QSAR or in vitro assays and improve validation methods.

Find ways to ensure that data gaps are filled.

Implement the policy that "no data means no market," meaning that chemicals for which safety data are not available are to be banned from sale or use.

Develop methods based on Bayesian approaches that can quantify dose response but also predict hazard. (Referring to "Bayesian" means using methods that can incorporate varying kinds of data and decision models and not rely solely on deterministic approaches such as modeling of dose-response relationships.)

Shift the expectations of the policy and legal communities for what science can deliver. The standards and barriers for making decisions are too high. There needs to be education to support use of the best available information to support decisions in the public interest, rather than insisting on an unachievable high bar for information to support such decisions.

Increase the budget for OEHHA.

III. What would you recommend that OEHHA do now to improve its ability to identify "safer" or "low hazard" chemicals? Would this be different from how it would identify "bad actor" chemicals?

Use the same general approaches to identify "safer" or "low hazard" chemicals as those used to identify "bad actor" chemicals. Identifying safer alternatives will require that knowledge gaps be addressed.

Develop/obtain/require the submission of information on all chemicals in use or proposed for use to determine which are safer or which are better alternatives. Such information is essential for making decisions on safer substitutes to use in place of high hazard chemicals that are being phased out. It would be important to think through the factors to consider, which would clearly include those we have been discussing like toxicity (and perhaps persistence or tendency to bioaccumulate). It might also be appropriate to consider broader factors such as energy efficiency of, or greenhouse gas emissions from, the production/use of a chemical/product. A life cycle analysis could be appropriate to address these issues.

Review and use the types of models that were discussed during the presentations to give some insight into what might be lower hazard.

Consider the use/application of a particular chemical as well as hazard in determining safer alternatives. This is related to the idea of scoping the factors to be addressed. There can be tradeoffs between hazard and characteristics that contribute to different forms of exposure, and the best tradeoff may differ with different uses.

Consider the needs and knowledge of users and how to involve them in developing safer chemical alternatives to ensure that the alternatives meet the specific need.

Consider ways to substitute chemicals with known hazards or unknown hazards with non-chemical approaches.

Look at case studies to sort out the factors that are useful and appropriate to consider in determining what is "safer." Perhaps the flame retardants would make a good case. Using some case studies and involving people from different perspectives would allow consideration of what different people might consider relevant, as well as how to do assessments.

Seek continuous improvement to achieving the "greenest" or "safest" possible results. We don't want to try to lock this in at a particular point in time but achieve continuous improvement as alternatives are developed and knowledge is improved.

Discuss how to define what is "safe" enough. You can't prove absolute safety.

Evaluate whether screening paradigms are sufficient to identify what's "safe." In labeling something a bad actor, a high level of evidence is required, so calling something "safe" should also use a high enough standard.

Cooperate with other agencies to develop and implement "high through-put" methods to develop data about more compounds and allow better knowledge for what is "safer." ("High through-put" methods are those such as genomic assays that can be run for many cases in a short time.)

Foster education to support the knowledge and skills to implement the ideas behind green chemistry and achieve safer alternatives.

IV. What would you recommend that OEHHA do to improve its ability to fill in data gaps for assessment now, without new empirical data (i. e. with QSARs, etc?).

Obtain the data collected by the CUPAs (Certified Unified Program Agencies), related to hazardous materials and requirements of the California Accidental Release Prevention Program. Such data are mostly now reported and stored on paper but need to be computerized. This could provide insight into chemical storage and use.

Request that companies operating in California submit copies of the information about chemicals that they submit to the European or Canadian governments.

Use creative methods to look at patterns of use of chemicals and expand knowledge base in this area.

Consider the use of a third party that could guarantee confidentiality for shared analysis and use of data to identify solutions to problems, especially with regard to use of data that might be considered confidential business information or proprietary data,. This would pertain primarily to arrangements between industry entities. There may be some models for this from the "nano" world.

Conduct a detailed assessment of the data requirements and data expected to emerge from the implementation of REACH. What can we expect to be produced? How much of it and what types are likely to be made publicly available? Can the state negotiate an agreement to review data that would be withheld as "confidential business information" under REACH and thereby at least make the data available for assessment? Perhaps the state could target data requirements toward areas not addressed or not addressed adequately under REACH.

Evaluate whether the agencies that implement REACH and/or the Canadian Environmental Protection Act could be identified as authoritative bodies under Proposition 65 so that the results under these

programs could be used by California to identify chemicals known to cause cancer or reproductive/developmental toxicity.

V. What would you recommend that OEHHA do to improve its ability to fill in data gaps for assessment over the longer term if the agency could require or compel or obtain new empirical data?

Create a unified database that includes data from sources around the world. This database would have to be designed to be accessible to different users (chemical products users; consumers, etc) and should be made public. (The "E-Chem" unified data portal newly introduced by OECD might be considered a "baby step" toward this.)

Ensure that data are available to the public and address limitations related to confidential business information.